



## PRESCRIBER'S UPDATE

Pain practitioners appropriately prescribe controlled substances as one means of providing pain relief for those who suffer from chronic pain. It is essential for prescribers of controlled substances to understand that there are risks associated with prescribing these agents and that it is essential to have rigorous adherence to state and federal controlled substance rules and regulations. With this in mind, I want to make you aware of three "sting" operations that have recently come to my attention as a means of providing instruction about the importance of prescribing controlled substances both cautiously and appropriately. Two of these "stings" involved the Drug Enforcement Administration and one involved State of California enforcement personnel. I want to alert readers to these enforcement actions to help pain practitioners recognize the warning signs that "something is not right."

The first sting scenario involves a rather healthy looking man in his mid-twenties presenting with vague complaints, but clearly stating that he feels better when he takes some particular controlled substance. If the pain practitioner delves more deeply into the history there are complaints about back pain. If the pain practitioner suggests that certain imaging studies need to be performed before any medications will be prescribed, the "patient" has the studies with him for the practitioner to review. Several skills are being checked in this encounter. The officer is seeing if the practitioner can obtain a history, in particular, a history about pain, not just about how people feel when they take opioid analgesics. The officer is checking to see if a physical examination is routinely performed. If there is no examination, how is the diagnosis accurately made? Is the practitioner able to read the imaging studies provided, that have been certified as "textbook normal" by the Chair of the local medical school Department of Radiology? Does the practitioner use an x-ray view box or just hold the films up to the nearest source of light? Does the practitioner say something like "I can see why you hurt from these films?" Does the practitioner get informed consent before prescribing controlled substances? Does the practitioner establish outcome criteria with the patient? Does the practitioner require the patient to sign an opioid agreement before providing controlled substances? Are "red flags" noted by the practitioner and adequately addressed? When the "patient" gets the third prescription from the practitioner the practitioner is in serious trouble.



The second sting scenario involves a rather healthy looking woman in her mid-twenties claiming to be a university student with endometriosis. She is an established patient of an OB-GYN "back home," and she is now having quite a bit of pelvic pain and this is interfering with her academic performance. She wants opioid analgesics to help her get by until she can return to her own physician. Her general examination is normal (if one is done) and she is not willing to have a pelvic examination performed at this time. When asked to sign a release of medical information so the pain practitioner can obtain her previous medical records and an opioid agreement for the use of the medication requested she says she wants to read them carefully before signing them. She is testing the practitioner to see if opioid prescribing practices are consistent and thorough. Assuming the practitioner agrees to give her

some medication to “tide her over” until she reviews the releases and the agreement, she will call back in a few days claiming she has used more medication than intended and needs more pills. She won’t return to pick up the prescription herself and won’t return the signed releases for medical information or the opioid agreement, but a man will appear in the practitioner’s office requesting the prescription for the “patient.” The office staff and the practitioner are being tested to see if prescriptions are released without good faith evaluations, in the absence of an opioid agreement and with failure to provide releases for outside medical records, to a person that has never been seen in your office before without being positively identified. If the second prescription is given the “patient” will call back in a few more days claiming to be on her way home, but still needing more medication. When the third prescription is given the practitioner gets to take a “perp walk” in handcuffs.

The third sting scenario is a variation of the first one I described. A healthy looking man presents with back pain and a history of consuming a fifth of whiskey per day for control of pain. He is accompanied by a woman (wearing a wire to record everything being said). He agrees to be physically examined and is perfectly normal (no guarding, tenderness, spasm, weakness, changes in DTRs, or any other physical findings whatsoever). Assuming that a plan of care is established involving the use of controlled substances (with or without an opioid agreement) he will return at the next visit reporting that the goals of treatment are met and he needs to continue the medication as prescribed (i.e. the practitioner told the patient his pain level would be reduced to a 3 on a 0-10 scale and the patient confirms that pain is now only at that level). More alarmingly, the patient will also report how effective the medicine was for the relief of the woman’s menstrual pain. The pain practitioner has just been told that the first attempt at treatment has been 100% successful (Is the practitioner really that good or just lucky?) and the patient is diverting some of the medication to another person. When the practitioner continues to prescribe and does nothing to stop the diversion or even question how likely it is that the first effort to address the pain has been so effective (and that the patient no longer needs any whiskey at all) the practitioner is on deck for the “perp walk.”

Do you see the patterns emerging? Healthy people are asking for opioid analgesics for less than clear reasons or are not being cooperative while superficially being agreeable. To lawfully prescribe controlled substances practitioners are expected to perform a good faith history and physical examination. Informed consent must be obtained as well, meaning that risks and benefits (along with alternatives) associated with therapy must be stated for the patient. Some criteria for efficacy (treatment outcome) must be established. There should be a review of previous medical records. There

should be ongoing monitoring of the treatment. There should be suspicion if things don’t add up or make sense to the practitioner. Blind acceptance of what patients tell practitioners should never occur when prescribing controlled substances.

Couple all of this with ignorance and you have another problem. How do patients lawfully obtain samples of Schedule 2 medications such as morphine, methadone, meperidine, oxycodone, hydromorphone or stimulants? Samples are not lawfully available for these types of medications. One possible problem could be that practitioners have received from their patients prescription medications that are no longer needed, not well tolerated or some other situation. By illegally diverting medication from one patient to another, practitioners often use left over medications from one patient to help another indigent one, or to spare the practitioner the need to write too many prescriptions while just trying new medications. The operative term is “illegally.” It is never lawful to give medication from one patient to another, no matter how tempting it may be to do so. Practitioners should refrain from accepting any medications back from patients once they are dispensed as lawful samples or obtained from a pharmacy with a prescription. It is not technically lawful to accept medication back from patients with the intention of flushing the medication down the toilet in the practitioner’s office (to witness the destruction) because doing so violates the federal clean water act. Medications returned to pharmacies are required to be received by a bonded reverse distributor for eventual destruction in an incinerator.

What about practitioners prescribing controlled substances to multiple members of the same family because one of them has medical insurance and other ones do not have insurance? Do not do this, regardless of the medical necessity. Each prescription for a controlled substance must be for a single patient. If members of the same family need similar medications, they all need their own unique prescriptions. Do not help family members divert medications within the family.

How are prescriptions issued in the practitioner’s absence? If the practitioner is on vacation or attending a meeting, how did the practitioner manage to place an original signature on the prescription form? Was the prescription signed in advance? Was the prescription post-dated? Never pre-sign any blank prescription forms. Never allow anyone else to prepare prescriptions on your blank forms without your permission and then only sign such forms after they are completed and you have checked them for accuracy. If refills will come due while you are away either arrange for proper coverage or provide patients with additional medication to cover the interval that you will be unavailable. Pharmacists know when prescribers are out of town and know when blank prescriptions have been signed in advance or post-dated. Federal law requires that prescriptions be dated on the date

they are issued. Post dating is absolutely never allowed. While federal law allows for the issuing of more than one Schedule 2 prescription at a time, many states require that prescriptions be filled within a specified time period (this will be the subject of a future article in this newsletter) so preclude the issuance of multiple Schedule 2 prescriptions to the same patient for the same medication at the same time.

These are but a few of the recent pitfalls that have caused problems for pain practitioners contacting the Academy for assistance related to their prescribing practices. Staying out of personal professional trouble with regulators, while effectively caring for patients suffering with pain, is not impossible to do. Careful attention to detail is required by prescribing practitioners along with adherence to applicable federal and state prescribing regulations. Those practitioners wanting to exercise their privilege (not their right) to prescribe controlled substances for the management of pain must assume that eventually they may be audited. Well documented histories and physical examinations, consistent use of opioid agreements, provision of informed consent, establishment of behaviorally measurable goals for treatment and tight internal practice standards will do much to protect practitioners and benefit patients with pain. Those believing that it is too much trouble to comply with the various statutes or having practice styles that are too busy to adequately evaluate patients should refrain from prescribing controlled substances.

Continue to read this newsletter for more information about controlled substance prescribing. The Academy intends to keep its members informed about prescribing trends and pain management practices.

### **Proper Disposal of Medications**

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Physicians frequently inquire about proper disposal of drugs, including controlled substances. There are two types of medications of which physicians may need to dispose—drugs that belonged to a patient and drugs or samples in the inventory of the physician.

**Patient Medications:** Physicians sometimes acquire drugs that belong to a patient either because the patient wanted to give them to someone else (didn't work, allergic, patient died, etc.) or the physician asked that they be brought to the office (to verify the count, to substantiate the need for new prescription, etc.). These drugs need to be destroyed and CANNOT legally be dispensed to another patient.

If the drug is a controlled substance, the medicine should

be destroyed in the presence of the patient or legal guardian. A controlled substance that has been dispensed to a patient may only be possessed by that patient—anyone else is in "illegal possession," which is a criminal offense. Documenting the disposal with a document can protect the physician from allegations of drug diversion. This document should include the patient's name stating that they voluntarily surrendered the medication(s) for disposal. It should include the name, strength and quantity of the drug with the patient/guardian signature and date. A statement giving the method of destruction and date should be included. This form should be witnessed with the signature of a licensed person and filed in the patient's record.

If the medication is not a controlled substance, possession by someone other than the patient is not a legal problem but similar documentation of the receipt and destruction is still recommended. This prevents the patient or family members from alleging that the physician is profiting from the patient's medication.

**Physician's Drugs or Samples:** Physicians frequently have samples or stock drugs that expire and need to be disposed of. Physicians, hospitals, clinics or pharmacies are NOT permitted to dispose of drugs by flushing (DEA and EPA regulation of businesses). Besides the legal issues, there are also the liabilities involved if a person obtains the drug from your trash and then has an adverse reaction or other type of injury. This scenario is not farfetched. There have been several instances in Kentucky of people retrieving drugs from dumpsters and landfills. Therefore, drugs need to be delivered to or picked up by a hazardous waste disposal company. The following methods of disposal may be used:

**Patient Owned Drugs:** Patients may dispose of their own medications in any way they choose. However, if this occurs in the physician's office, the drugs should be rendered unusable first. The best method for pills is to dissolve in hot water and flush down the toilet. Liquids and injectables can be flushed directly.

**Physician Owned Drugs:** Physicians who have drugs or samples may dispose of them by utilizing a disposal company. A list of companies who can dispose of controlled substances and non-controlled substances may be obtained at [http://publichealth.state.ky.us/drug\\_control.htm](http://publichealth.state.ky.us/drug_control.htm). If only non-controlled are involved, you may wish to talk to your current hazardous waste contractor. They may be able to take care of drugs with other items at minimal cost.